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**FOR IMMEDIATE RELEASE**

**NNFA Testifies at FDA Hearing on New Dietary Ingredients**

**WASHINGTON, D.C. (November 15, 2004)** – David Seckman, executive director and CEO of the National Nutritional Foods Association (NNFA), was among those testifying at a public meeting on pre-market notification of new dietary ingredients (NDI) held today by the Food and Drug Administration (FDA). According to the agency, it is seeking public comment on several issues to help clarify the requirements of NDI submissions as contained in section 413 (a) (2) of the Food, Drug and Cosmetic Act. A new dietary ingredient is defined as one that was not marketed prior to the passage of the Dietary Supplement Health and Education Act of 1994. Before such ingredients can be marketed, safety data must be reviewed and accepted by the FDA.

“What everyone in the industry needs is clear guidance,” Seckman testified.

“Specifically, NNFA believes that as written, section 413 is unclear both as to when a new dietary ingredient notification is required and the type of information to be included if a premarket notification is filed.”

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In fact, NNFA had previously voiced its thoughts in comments to FDA dated May 9, 2002, suggesting ways for FDA to enhance the quality, utility and clarity of the premarket notification requirement for a NDIs.

"We continue to believe that FDA can use public comments on section 413 to provide the industry with much needed guidance on NDI submissions," Seckman stated in his testimony. "Of course, any guidance will apply to any company putting dietary ingredients on the market – whether they be the manufacturers of finished products or raw ingredient suppliers who need to guarantee safety to their customers."

*(Complete testimony is available for download at:*

*<http://www.nnfa.org/services/government/comments.htm#comments>)*

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#### **About NNFA**

NNFA ([www.nnfa.org](http://www.nnfa.org)) is the nation's largest and oldest non-profit organization dedicated to the natural products industry. NNFA represents more than 8,000 retailers, manufacturers, wholesalers and distributors of natural products including foods, dietary supplements, and health and beauty aids. In addition to offices in Washington D.C., and Newport Beach, Calif., NNFA also has seven regional offices throughout the United States and is governed by a 22-member board of directors representing all segments of industry.



*National Nutritional Foods Association*

**Testimony of David Seckman**  
**National Nutritional Foods Association**  
**November 15, 2004**

My name is David Seckman, and I am the Executive Director of the National Nutritional Foods Association (NNFA). I very much appreciate being able to submit this testimony to the Food and Drug Administration (FDA) in response to the October 20, 2004 announcement in the Federal Register about the Public Meeting on premarket notification for new dietary ingredients (NDIs) under section 413 of the Federal Food Drug and Cosmetic Act.

NNFA is a trade association representing the interests of more than 8,000 retailers, manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products throughout the United States. NNFA has consistently supported FDA's ability and efforts to enforce the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and to ensure that dietary supplements continue to be safe.

In fact, NNFA previously voiced its thoughts in comments to FDA dated May 9, 2002. There, NNFA suggested ways for FDA to enhance the quality, utility and clarity of the Premarket Notification Requirement for a NDI under section 413. We continue to believe that FDA can use public comments on section 413 to provide the industry with much needed guidance on NDI submissions. Of course, any guidance will apply to any company putting dietary ingredients on the market – whether they be the manufacturers of finished products or raw ingredient suppliers who need to guarantee safety to their customers.

What everyone in the industry needs is clear guidance. Specifically, NNFA believes that as written, section 413 is unclear both as to: when a New Dietary Ingredient notification is required; and the type of information to be included if a premarket notification is filed. In light of FDA's November 4 publication of its major initiatives for dietary supplements, NNFA specifically urges FDA to use caution in enforcing on NDI issues before it offers clarification to industry as to when a premarket submission is required.

**Specific Points that Should Be Addressed**

Although NNFA will be commenting in more detail, following are some key issues that we believe must be carefully and fully addressed through the guidance:

## I. **Status of Certain Substances as NDI**

### A. Not Chemically Altered Exemption

According to section 413(a)(1), a dietary supplement containing an NDI is not adulterated if: “the dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food *in a form in which the food has not been chemically altered*.” Thus, that chemically unaltered ingredients from the food supply *do not* require NDI filings to be made before being used in dietary supplements.

The legislative history of DSHEA offers a small bit of clarification on what is meant by “chemically altered”: “the term ‘chemically altered’ does not include the following physical modifications: minor loss of volatile components, dehydration, lyophilization, milling, tincture or solution in water, slurry, powder, or solid in suspension.” 140 Cong. Rec. H1180 (daily ed. Oct. 6, 1994).

Clearly, many forms of processing have been left off this list – and FDA has not offered industry guidance as to how to determine whether a process would or would not be considered chemical alteration.

NNFA takes the position that a dietary ingredient should fall within this “not chemically altered” exemption *as long as the resulting dietary ingredient is found in nature*. Supplements are a subset of food and need to be regulated accordingly. If it can be shown that an ingredient, either as a single entity or complex, can be found in our diets and there is no evidence of ill effects; that ingredient should be allowed for sale. Moreover, FDA should not assume that changes in processing or formulation always result in a change in the chemical structure that would require a NDI filing. Such an interpretation is consistent with the intent of section 413 in that it would exempt entities with known safety records, based on food use, from the NDI premarket submission requirement.

### B. Components of Foods

Section 413 is unclear as to whether components of foods, such as the lycopene found in tomatoes, are subject to the premarket notification requirement.

NNFA takes the position that components should be also subject to the “not chemically altered” exemption in section 413(a)(1). Thus, if the extraction method used to isolate components does not result in chemical alteration of the component, that component should be exempt from the NDI filing requirement.

Moreover, the 413(a)(1) exemption should extend to components that *are* chemically altered during the extraction process, but are in a form that is found in nature. Such compounds again have proven safety within the food supply.

## **II. Chemical Identification**

In its Federal Register notice regarding this meeting, FDA raised numerous questions regarding how the NDI substance should be chemically identified.

NNFA takes the position that chemical identification of a substance must reflect the level of variation of the substance that is found in nature. For example, botanical ingredients vary in composition, depending on where in the world they are grown. Certainly, the agency should not require an NDI notification for each region unless there are significant differences that result in a safety issue.

In addition, other ingredients may vary as percentages of certain conformations. Again, however, this level of difference should not trigger new NDI requirements – as long as the variation reflects that which is found in nature.

## **III. Information about the Dietary Supplement**

In its Federal Register notice FDA raised the question of what types of information about the dietary supplement product should be included in an NDI notification, and specifically raised questions about conditions of use and labeling.

NNFA would like to point out that when the agency raises such questions, it blurs the lines between an NDI and a dietary supplement product as a whole. FDA should not be concerned with how an ingredient was used (unless it was previously used as a drug, raising other sections of DSHEA), or how it is labeled. This information does not go to the safety of the dietary ingredient, and should not alter the review process as to whether a specific dietary ingredient is safe for use.

## **IV. Establishing an Reasonable Expectation of Safety**

### **A. History of Use**

FDA raised the question of what quality and quantity of data and information are needed to establish a reasonable expectation of safety based upon history of use.

NNFA takes the position that FDA should establish clear parameters regarding what kinds of evidence would sufficiently demonstrate “reasonable evidence of safety”. However, NNFA cautions that FDA’s guidelines should not be so rigid as to establish inflexible requirements. The kinds of data available for dietary ingredients vary widely – from very long documented history of use, to clinical studies, to observational reviews. The kinds of data available may also change over time. NNFA is concerned that the NDI process, along with FDA’s recently issued initiatives, does not become a mechanism to stifle or halt NDI submissions by presenting an almost insurmountable barrier for acceptance.

To adequately reflect this reality, FDA should continuously exercise flexibility in the types of evidence required – for example, where an NDI does not have a

long history of consumption by humans such as novel extracts of grandfathered botanicals. Moreover, an NDI that is an extract from an old dietary ingredient and is significantly similar to the old dietary ingredient might require less safety data than a new, synthetic substance. To respond otherwise would result in a stifling of research and development for these ingredients.

#### B. Other than a History of Use

FDA also raises the question of what quality and quantity of data and information are needed to establish a reasonable expectation of safety based upon information *other* than a history of use.

Here, NNFA would simply like to point out that while a certain amount of scientific evidence is certainly necessary to establish safety – the burden should not be so high as to mirror a drug safety review. NNFA submits that information to establish a reasonable expectation of safety should suffice. This may include animal and in vitro studies conducted in an appropriate model, LD 50, and an Ames Test.

#### C. Grandfathered Ingredients

FDA has specifically questioned what types of documentation are necessary to establish that an ingredient was “marketed in the U.S. before October 15, 1994”, and is thus grandfathered. NNFA and other industry groups, in 1994, took the lead in developing lists that reflected products marketed in or prior to 1994. Those lists have been relied upon by industry, industry lawyers and consultants, and presumably even FDA. NNFA submits that these have achieved authoritative status, and should continue to be available to be relied upon for confirming grandfathered status.

In addition, if an ingredient is not listed on one of these lists, it may still be grandfathered if there is evidence of marketability pre-October 1994. Examples of such evidence include, for example, human studies, product advertisements, product catalogues, order forms, and invoices.

### V. **Conclusion**

NNFA appreciates the opportunity to comment on the NDI process.